K023769

DEC 3 0 2002

510(k) SUMMARY

Date:	**November 6, 2002**
Manufacturing Facility:	APPRO Healthcare, Inc. 847 Main Street Buffalo, NY 14203
Telephone:	(716) 855-1068
Contact Person:	John R. Semler Vice President, RD&E Extension 309 Email: jrsemler@approhealthcare.com
Device Trade Name:	Prepare™ Administration Set
Device Common Name:	Administration Set
Classification Name:	Intravascular Administration Set
Regulatory Reference:	FPA
Predicate Device	CADD® Administration Set

Description:

Prepare™ Administration Set is designed for use with Deltec CADD®-1, CADD®-Plus, and CADD®-PCA pumps. The device provides the interface with the pump and a sterile fluid path from an infusion fluid container to a patient's access catheter.

Intended Use / Indications for Use:

Prepare™ Administration Set is intended for the administration of various medical solutions from a fluid container to the patient's access catheter, and is used only with Deltec CADD®-1, CADD®-Plus, and CADD®-PCA pumps. Intended for intravenous, intra-arterial, subcutaneous, epidural, and subarachnoid administration.

Prepare™ Administration Set is indicated for use in acute and alternate site care settings. Alternate site care includes, but is not limited to, infusion clinics, nursing homes, and home healthcare.

Physical/Technical Comparison

Prepare™ Administration Set can be used in place of CADD® Administration Set. Physical and technical characteristics, including materials used in construction, size, intended use and ability to interface with specified CADD® pumps, are comparable.

Performance Summary:

The device and the predicate were subjected to various bench tests to demonstrate comparable performance characteristics. Prepare™ Administration Set's accuracy of delivery, volume delivered per pump cycle, and fit to pump are substantially equivalent to the CADD® Administration Set.

Biocompatibility Testing:

Prepare™ Administration Set device was subjected to biocompatibility testing as recommended by ISO-10993-1, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.* The device is certified as non-irritating, non-cytotoxic, non-toxic, non-hemolytic, and non-sensitizing.

Sterility:

Prepare™ Administration Set is sterilized by ethylene oxide gas in a validated sterilization process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

Mr. John R. Semler
APPRO Healthcare, Incorporation
847 Main Street
Buffalo, New York 14203

Re: K023769
Trade/Device Name: Prepare™ Administration Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 6, 2002
Received: November 12, 2002

Dear Mr. Semler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023769

510(k) Number, if known: ~~Not yet assigned~~ K023769

Device Name: Prepare™ Administration Set

Indications for Use:

Prepare™ Administration Set is intended for the administration of various medical solutions from an IV container to the patient's access catheter and is used only with Deltec CADD®-1, CADD®-Plus, and CADD®-PCA pumps. Intended for intravenous, intra-arterial, subcutaneous, epidural, and subarachnoid administration.

Prepare™ Administration Set is indicated for use in acute and alternate site settings. Alternate sites include, but are not limited to, infusion clinics, nursing homes, and home healthcare.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

OR

Over-the-Counter Use ____________(Per 21CFR 801.109)

William M. Burdick for Patricia Cricenti

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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